



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. FDA-2013-N-1282]

National Environmental Policy Act; Environmental Assessments for Tobacco Products;

Categorical Exclusions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA) and the Council on Environmental Quality (CEQ) Regulations Implementing NEPA (CEQ regulations), the Food and Drug Administration (FDA or the Agency) is issuing a final rule to revise its NEPA implementing regulations to provide categorical exclusions for certain actions related to substantial equivalence (SE) reports, SE exemption requests, and tobacco product applications, and the rescission (order withdrawing an order) or suspension of orders regarding the marketing of tobacco products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA is also amending its NEPA implementing regulations to include tobacco products, where appropriate, in light of its new authority under the Tobacco Control Act.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Gerie Voss or Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373; gerie.voss@fda.hhs.gov or katherine.collins@fda.hhs.gov.

Executive Summary

Purpose of the Final Rule

This final rule will allow certain classes of actions on tobacco product marketing applications to be excluded from the requirements to prepare an environmental assessment (EA) or an environmental impact statement (EIS). FDA is also amending its NEPA implementing regulations to include tobacco products, where appropriate, in light of its new authority under the Tobacco Control Act (Pub. L. 111-31).

Legal Authority

FDA is issuing this final rule under NEPA and CEQ regulations (42 U.S.C. 4332(2); 40 CFR parts 1500 to 1508) requiring FDA to assess, as an integral part of its decisionmaking process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed. FDA regulations governing its responsibilities under NEPA are codified at part 25 (21 CFR part 25), and CEQ regulations are codified at 40 CFR parts 1500 to 1508.

Summary of the Major Provisions

This final rule applies to certain classes of tobacco product-related actions including:

- (1) Issuance of an order finding a tobacco product substantially equivalent under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C.

387j(a)(2)(B)); (2) issuance of an order finding a tobacco product not substantially equivalent under section 910(a) of the FD&C Act, denial of a request for an exemption under 21 CFR part 1107 (part 1107) from the requirement of demonstrating substantial equivalence, issuance of an order under section 910(c) of the FD&C Act that a new tobacco product may not be introduced or delivered for introduction into interstate commerce, or issuance of an order under section 911 of the FD&C Act (21 U.S.C. 387k) that a modified risk tobacco product (MRTP) may not be introduced or delivered for introduction into interstate commerce; (3) rescission (order withdrawing an order) or temporary suspension of an order authorizing the marketing of a new tobacco product under section 910 of the FD&C Act; (4) rescission of an order authorizing the marketing of a MRTP under section 911 of the FD&C Act; and (5) rescission of an order granting an exemption request under § 1107.1 (21 CFR 1107.1).

This final rule provides that certain classes of actions are categorically excluded from the requirement to prepare an EA or EIS unless extraordinary circumstances are present such that the specific proposed action may have the potential to significantly affect the quality of the human environment. The rule also amends FDA's NEPA implementing regulations to include tobacco products in sections dealing with statements about disclosure regarding certain FDA actions and preparation of an EIS.

I. Background and Legal Authority

NEPA and CEQ regulations require each Federal Agency to assess, as an integral part of its decisionmaking process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed (42 U.S.C. 4332(2); 40 CFR 1506.6). CEQ is responsible for CEQ regulations and for overseeing Federal

efforts to comply with NEPA. Both FDA and CEQ have issued regulations governing Agency obligations and responsibilities under NEPA. FDA regulations are codified at part 25 and CEQ regulations are codified at 40 CFR parts 1500 to 1508.

CEQ regulations, which are binding on all Federal Agencies, establish procedures for implementing NEPA. Agencies may adopt procedures to supplement CEQ's regulations. In adopting NEPA-implementing procedures, Federal Agencies are directed by CEQ to reduce paperwork (40 CFR 1500.4 and 1500.2(b)) and to reduce delay (40 CFR 1500.5) by using several means, including the use of categorical exclusions. CEQ regulations also state that Agencies shall continue to review their policies and procedures and, in consultation with CEQ, revise them as necessary to ensure full compliance with the purpose and provisions of NEPA (40 CFR 1507.3).

FDA regulations state that for major Federal actions that may "significantly affect the quality of the human environment," FDA must prepare an EIS (§ 25.22 (21 CFR 25.22); see also 40 CFR 1501.4). The term "significantly," as used in NEPA, requires considerations of both "context" (i.e., analyzed in several contexts) and "intensity" (i.e., severity of impact) (40 CFR 1508.27(a), (b)). If the action may have a significant environmental impact, FDA can either prepare an EIS or prepare an EA. An EA provides sufficient information and analysis for FDA to determine whether to prepare an EIS or issue a finding of no significant impact (§ 25.20; 40 CFR 1501.4). FDA is responsible for the scope and content of an EA and generally requires an applicant to prepare an EA and make necessary corrections to it (§ 25.40(b)).

Categorically excluded actions refer to a category of actions that have been found not to individually or cumulatively have a significant effect on the quality of the human environment and which do not normally require the preparation of an EA or EIS (40 CFR 1508.4). However,

as required under § 25.21 and 40 CFR 1508.4, FDA will require preparation of at least an EA for any specific action that normally would be excluded if extraordinary circumstances are present such that the specific proposed action may have the potential to significantly affect the quality of the human environment.

If a submitter elects to request a categorical exclusion for a proposed action, a claim of categorical exclusion must be submitted in accordance with § 25.15. Section 25.15 requires that the claim of categorical exclusion include: (1) A statement of compliance with the categorical exclusion criteria and (2) a statement that, to the submitter's knowledge, no extraordinary circumstances exist.

In November 2010, CEQ issued a final guidance on categorical exclusions including the process Federal Agencies should use to establish new categorical exclusions. The guidance states that Agencies can establish new categorical exclusions to reduce paperwork and delay where the Agency has developed a record illustrating that the proposed categorical exclusion covers a category of action that, on the basis of past experience, does not normally have the potential to cause significant environmental effects (Ref. 1 at pp. 2 and 16; 40 CFR 1508.4). In addition, when Agencies acquire new responsibilities through legislation or administrative restructuring, they should propose new categorical exclusions after they, or other Agencies, gain sufficient experience with the new activities to make a reasoned determination that any resulting environmental impacts are not significant (Ref. 1 at p. 18).

FDA is issuing new categorical exclusions in accordance with NEPA, FDA, and CEQ regulations, and the CEQ November 2010 categorical exclusion guidance. In the Federal Register of January 23, 2014 (79 FR 3742), FDA issued a notice of proposed rulemaking (NPRM) to categorically exclude certain tobacco product application actions from the

requirement to conduct an EA or EIS unless extraordinary circumstances are present such that the specific proposed action may have the potential to significantly affect the quality of the human environment. The NPRM also sought to amend FDA's NEPA implementing regulations to include tobacco products. This final rule includes these categorical exclusions and amends FDA's NEPA implementing regulations.

The final rule is issued under 42 U.S.C. 4332(2) and 40 CFR 1507.3, which requires FDA to assess, as an integral part of its decisionmaking process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment and to ensure that the interested and affected public is appropriately informed (42 U.S.C. 4332(2); 40 CFR 1506.6).

II. Overview of the Final Rule

FDA considered all of the comments it received regarding the proposed rule and is finalizing it with three changes. We have changed the text of § 25.20(o) in the final rule to clarify that granting a request for an exemption under part 1107 from the requirement of demonstrating substantial equivalence normally requires the preparation of an EA, unless it is subject to a categorical exclusion. Similarly, we have changed the text of § 25.35(b) to clarify that denial of a request for an exemption under part 1107 from the requirement of demonstrating substantial equivalence is categorically excluded and, therefore, normally does not require the preparation of an EA or an EIS. We have also made a technical change by replacing the term "ordinarily" with "normally" in §§ 25.20 and 25.35 to conform with 40 CFR 1508.4. The Agency considers these terms, as used in these regulations, to be synonymous. FDA will continue to evaluate the need for this conforming amendment to other FDA regulations in part 25 as the FDA regulations are updated.

In addition, § 25.20(o) in the final rule replaces proposed § 25.20(p) (Issuance of an order finding a tobacco product substantially equivalent under the FD&C Act, unless categorically excluded under § 25.35) and § 25.20(p) replaces § 25.20(q) (Issuance of an order authorizing marketing of a new tobacco product under section 910 of the FD&C Act or an order authorizing marketing of a modified risk tobacco product under section 911 of the FD&C Act, unless categorically excluded under § 25.35).

The Agency has prepared EAs for many Agency-initiated actions and has reviewed hundreds of EAs for a variety of industry requests for Agency action on foods, drugs, and medical devices for human consumption and use, and foods and drugs given to animals. In accordance with § 25.40(a), these EAs have focused on the potential environmental effects related to the use and disposal from use of FDA-regulated articles. Based on FDA's experience reviewing EAs for actions involving foods, drugs, and medical devices for human consumption and use, and food and drugs given to animals, and its evaluation and knowledge of other relevant environmental science, FDA has determined that certain classes of actions related to tobacco products normally do not cause significant environmental effects and, therefore, should be added to the list of actions that are excluded from the requirement to prepare an EA or an EIS. In addition, FDA has gained sufficient experience from its responsibilities under the Tobacco Control Act to determine that certain actions on tobacco-related applications do not result in significant environmental impacts to the quality of the human environment. Accordingly, FDA is adding several new categorical exclusions for tobacco product-related actions.

With this final rule, FDA is adding the following classes of tobacco product-related actions that qualify for categorical exclusions: (1) Issuance of an order finding a tobacco product substantially equivalent to a tobacco product commercially marketed in the United States as of

February 15, 2007, under section 910(a)(2)(B) of the FD&C Act; (2) issuance of an order finding a tobacco product not substantially equivalent under section 910(a) of the FD&C Act, denial of a request for an exemption under part 1107 from the requirement of demonstrating substantial equivalence, issuance of an order under section 910(c) of the FD&C Act that a new tobacco product may not be introduced or delivered for introduction into interstate commerce, or issuance of an order under section 911 of the FD&C Act that a MRTP may not be introduced or delivered for introduction into interstate commerce (a MRTP is any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products); (3) rescission (order withdrawing an order) or temporary suspension of an order authorizing the marketing of a new tobacco product under section 910 of the FD&C Act; (4) rescission of an order authorizing the marketing of a MRTP under section 911 of the FD&C Act; and (5) rescission of an order granting an exemption request under § 1107.1.

III. Comments on the Proposed Rule

FDA received 10 comments on the proposed rule. Comments were received from tobacco product manufacturers, environmental groups, and individuals. To make it easier to identify comments and our responses, the word “Comment,” in parentheses, will appear before each comment, and the word “Response,” in parentheses, will appear before each response. We have numbered the comments to make it easier to distinguish between comments; the numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with them. We have combined similar comments under one numbered comment. In addition to the comments specific to this rulemaking that we address in the following paragraphs, we received five general comments: (1) One expressing a view that all

tobacco products should be prohibited; (2) another providing reasons why FDA should regulate tobacco products and tobacco marketing; (3) one opposing any regulation that decreases FDA authority; (4) one supporting another comment; and (5) one that stated general disagreement with FDA proposing rules for this policy. These comments express broad policy views and do not address specific points related to this rulemaking. Because these general comments fall outside the scope of the proposed rule, we do not address them here. The remaining comments and FDA's responses follow.

(Comment 1) Multiple comments addressed the classes of tobacco actions FDA proposed to qualify for categorical exclusions. Several comments did not want FDA to categorically exclude any class of actions from the requirement to prepare an EA or EIS. These comments stated that the tobacco industry has misrepresented facts and relevant information regarding adverse impacts of its tobacco products and cannot be trusted to determine whether extraordinary circumstances are present such that the specific proposed action may have the potential to significantly affect the quality of the human environment.

(Response) We disagree with these comments. FDA is categorically excluding those actions that FDA has determined, based on experience, will not significantly affect the quality of the human environment. Additionally, this final rule will require a person submitting a tobacco product application to certify that the application qualifies for a categorical exclusion. FDA may deny the application if the submitter makes a false certification. In addition, under section 1001 of title 18 of the United States Code, anyone who makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties. FDA, therefore, will continue to have appropriate oversight of the environmental impacts of tobacco product applications that are the subject of this final rule.

(Comment 2) Other comments expressed support for the rule and recommended that FDA add additional categorical exclusions for marketing authorizations for products that are the subject of SE reports under section 910(a)(2)(A) (nonprovisional SE reports) and SE exemption requests under section 905(j)(3) of the FD&C Act (21 U.S.C. 387e(j)(3)). These comments stated that FDA's analysis in support of the proposed rule should apply to these actions as well.

(Response) We disagree. As we stated in the proposed rule, FDA expects that any new tobacco product that receives marketing authorization through any of the available premarket pathways will have less--or no more--environmental impact than do tobacco products currently on the market. However, FDA does not yet have data to determine whether these actions, in the aggregate, will significantly impact the environment. Actions on provisional SE reports, by contrast, will relate only to products already on the market. Therefore, FDA is not proposing to add such categorical exclusions at this time.

(Comment 3) Comments provided several reasons why they believe categorically excluding nonprovisional SE reports and SE exemption requests from the requirement to develop an EA or EIS for tobacco products will not significantly affect the quality of the human environment. First, comments stated that marketing authorizations for products that are the subject of nonprovisional SE reports and SE exemption requests will not lead to a larger overall tobacco product market or expand tobacco product consumption; and tobacco products found SE or exempt from SE will compete with or replace tobacco products currently on the market. In addition, comments estimated that the number of new tobacco products for which FDA issues SE orders (for nonprovisional SE reports under section 910(a)(2)(A) of the FD&C Act) or grants SE exemptions would be relatively small.

Second, comments urged FDA to categorically exclude the granting of SE exemption requests because they believe the foreseeable environmental effects are even less significant for SE exemptions than for nonprovisional SE reports, based upon the more limited circumstances in which a product would be eligible for a request for an SE exemption.

Third, comments stated that authorizing categorical exclusions for marketing authorizations for products that are the subject of nonprovisional SE reports and SE exemption requests would be consistent with FDA's regulatory approach to premarket clearances and approvals for other product categories regulated by the Agency. Comments also maintained that the tobacco industry's previous experience with EAs for tobacco product applications demonstrates that these tobacco products are unlikely to significantly affect environment.

Fourth, a comment suggested that the extraordinary circumstances provision of the proposed rule supports inclusion of other classes of tobacco actions because it provides a mechanism by which to prevent any SE report or SE exemption request from resulting in the exposure of substances harmful to some biological mechanisms or systems in the environment or cause harm to a protected or endangered species.

(Response) We disagree with these comments. CEQ has provided guidance to Federal Agencies for substantiating a new or revised categorical exclusion. In this guidance, CEQ explains that Federal Agencies should propose new categorical exclusions after they, or other Agencies, "gain sufficient experience with new activities to make a reasoned determination that any resulting environmental impacts are not significant." At this time, FDA is not yet able to effectively evaluate whether these classes of actions will lead to a larger overall tobacco product market or expand tobacco product consumption. A finding of SE for products that are the subject of a nonprovisional SE report, while comparing one tobacco product to another for

characteristics and public health impact, does not account for the environmental impact of many determinations in the aggregate. FDA will continue to monitor submissions and will consider issuing a new proposed rule if the Agency determines that additional tobacco product actions should be categorically excluded, in the absence of extraordinary circumstances, from further analysis in an EA or EIS.

(Comment 4) One comment stated that FDA should revise the examples provided in the preamble of the proposed rule regarding circumstances where a categorical exclusion would not be appropriate for tobacco products. This comment stated that FDA paraphrases two extraordinary circumstances examples provided in the regulations (at § 25.21(a) and (b)) and unnecessarily expands the scope of these provisions.

(Response) We disagree with this comment's characterization of FDA's discussion of extraordinary circumstances. FDA's description in the preamble provided circumstances for which EA or EIS preparation may be required for tobacco product applications. The descriptions were not intended to expand the existing regulations on extraordinary circumstances (§ 25.21 Extraordinary circumstances) but, rather, to apply them to tobacco product applications. As set forth in § 25.21, FDA will require preparation of at least an EA for an action that would normally be categorically excluded if extraordinary circumstances are present such that the proposed Agency action may have the potential to "significantly" affect the quality of the human environment. The "protected or endangered species" mentioned in the preamble to the proposed rule will continue to be those determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened or wild flora or fauna that are entitled to special protection under some other Federal law, as stipulated at § 25.21(b). As stated in the preamble of the proposed rule, FDA will

continue to rely upon consideration of the intensity and context as set out at 40 CFR 1508.27 for determining whether an extraordinary circumstance is present and a proposed action may have the potential to significantly affect the environment (79 FR 3742 at 3746).

(Comment 5) Two comments questioned FDA's assertion that tobacco product waste is "individually and cumulatively trivial" and asserted that FDA did not review a sufficient number of studies. These comments urged FDA to not finalize the proposed rule based on the environmental impact of tobacco product waste. They noted that the growing of tobacco and manufacturing of cigarettes may result in a variety of pesticides, herbicides, insecticides, fungicides, and rodenticides being deposited into the environment, and 4,000 chemicals may be introduced to the environment via tobacco product waste, thirdhand, and secondhand smoke. One comment stated that the environmental impacts of tobacco product manufacture and disposal are best addressed by having FDA retain the lead role in preparing any necessary EISs or EAs.

(Response) FDA disagrees with comments stating that it did not adequately consider the environmental impact of tobacco product waste. FDA reviewed the 2011 Toxics Release Inventory National Analysis to determine that the amount of waste released, recycled, and treated due to the manufacturer of all tobacco products currently on the market is a fraction of the total toxic waste released from and managed by industrial facilities in the United States. The classes of actions that FDA proposed for categorical exclusions do not result in additional tobacco products being marketed because those exclusions represent either the marketing authorization of tobacco products already on the market (provisional SE reports), or the rescission, suspension, or denial of authorization for a new tobacco product. As mentioned in the proposed rule, FDA also reviewed the effect on the environment due to the use (including

secondhand and thirdhand smoke) and disposal of tobacco products (including cigarette butts) currently on the market. FDA acknowledged that currently marketed tobacco products contribute to pollution on beaches and streets and affect wildlife and marine and freshwater fish. FDA concluded from its review that the effects of keeping tobacco products on the market are individually and cumulatively trivial compared to the existing environmental effects due to toxic waste released from and managed in industrial facilities in the United States and the existing environmental effects due to the use and disposal from use of the tobacco products in the country (79 FR 3742 at 3745). FDA has carefully considered the information available in order to conclude that these tobacco product actions qualify for categorical exclusion under NEPA.

V. Environmental Impact

The amendment of FDA's NEPA regulations (part 25) concerns NEPA documentation for certain actions on tobacco product submission. CEQ does not direct Federal Agencies to prepare a NEPA analysis or document before establishing Agency procedures that supplement CEQ regulations for implementing NEPA. Agencies are required to adopt NEPA procedures that establish specific criteria for, and identification of, three classes of actions: (1) Those that require preparation of an EIS; (2) those that require preparation of an EA; (3) and those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). Categorical exclusions are one part of those Agency procedures; therefore, establishing categorical exclusions does not require preparation of a NEPA analysis or document. Agency NEPA procedures, such as FDA's NEPA regulations, assist FDA in the fulfillment of Agency responsibilities under NEPA, but are not FDA's final determination of what level of NEPA analysis is required for a particular proposed action on a tobacco product submission. The requirements for establishing Agency NEPA procedures are set forth at 40 CFR 1505.1 and 1507.3. Furthermore, the Agency has also

determined under § 25.30(h) that this rulemaking does not individually or cumulatively have a significant effect on the quality of the human environment.

VI. Analysis of Impacts

The final regulatory impact analysis is available as Reference 2 in Docket No. FDA-2013-N-1282 (Ref. 2) and at

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. Council on Environmental Quality, “Final Guidance for Federal Departments and Agencies on Establishing, Applying, and Revising Categorical

Exclusions Under the National Environmental Policy Act,” 76 FR 3843, January 21, 2011.

2. Statement of RADM David Ashley, Ph.D. and Hoshing Chang, Ph.D., “Impact of Tobacco Products on the Environment.”

List of Subjects in 21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR part 25 is amended as follows:

PART 25--ENVIRONMENTAL IMPACT CONSIDERATIONS

1. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262, 263b-264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500-1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531-533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123-124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356-360.

§ 25.15 [Amended]

2. Amend § 25.15 as follows:

- a. In paragraph (a), remove “or 25.34,” and add in its place “25.34, or 25.35,”;
- b. In paragraph (c), remove “or 25.34” and add in its place “25.34, or 25.35”; and
- c. In paragraph (d), remove “or 25.34,” and add in its place “25.34, or 25.35,”.

3. Amend § 25.20 by revising the introductory text and by adding paragraphs (o) and (p) to read as follows:

§ 25.20 Actions requiring preparation of an environmental assessment.

Any proposed action of a type specified in this section normally requires at least the preparation of an EA, unless it is an action in a specific class that qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, 25.34, or 25.35:

* * * * *

(o) Issuance of an order finding a tobacco product substantially equivalent under the Federal Food, Drug, and Cosmetic Act, or granting of a request for an exemption under 21 CFR part 1107 from the requirement of demonstrating substantial equivalence, unless categorically excluded under § 25.35.

(p) Issuance of an order authorizing marketing of a new tobacco product under section 910 of the Federal Food, Drug, and Cosmetic Act or an order authorizing marketing of a modified risk tobacco product under section 911 of the Federal Food, Drug, and Cosmetic Act, unless categorically excluded under § 25.35.

§ 25.30 [Amended]

4. Amend the introductory text of § 25.30 by removing “25.34” and adding in its place “25.35”.

5. Add § 25.35 to subpart C to read as follows:

§ 25.35 Tobacco product applications.

The classes of actions listed in this section are categorically excluded and, therefore, normally do not require the preparation of an EA or an EIS:

(a) Issuance of an order finding a tobacco product substantially equivalent under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act;

(b) Issuance of an order finding a tobacco product not substantially equivalent under section 910(a) of the Federal Food, Drug, and Cosmetic Act, denial of a request for an exemption under 21 CFR part 1107 from the requirement of demonstrating substantial equivalence, issuance of an order under section 910(c) of the Federal Food, Drug, and Cosmetic Act that a new tobacco product may not be introduced or delivered for introduction into interstate commerce, or issuance of an order under section 911 of the Federal Food, Drug, and Cosmetic Act that a modified risk tobacco product may not be introduced or delivered for introduction into interstate commerce;

(c) Rescission or temporary suspension of an order authorizing the marketing of a new tobacco product under section 910 of the Federal Food, Drug, and Cosmetic Act;

(d) Rescission of an order authorizing the marketing of a modified risk tobacco product under section 911 of the Federal Food, Drug, and Cosmetic Act; and

(e) Rescission of an order granting an exemption request under § 1107.1 of this chapter.

§ 25.40 [Amended]

6. Amend § 25.40 by removing from paragraph (a) “or § 25.34” and adding in its place, “§ 25.34, or § 25.35.”

7. Amend § 25.50 by revising the first, third, fourth, and fifth sentences of paragraph (b) to read as follows:

§ 25.50 General information.

* * * * *

(b) Many FDA actions involving investigations, review, and approval or market authorization of applications, and premarket notifications for human drugs, animal drugs, biologic products, devices, and tobacco products are protected from disclosure under the Trade Secret Act, 18 U.S.C. 1905, and section 301(j) of the Federal Food, Drug, and Cosmetic Act.

* * * Even the existence of applications for human drugs, animal drugs, biologic products, devices, and tobacco products is protected from disclosure under these regulations. Therefore, unless the existence of applications for human drugs, animal drugs, biologic products, tobacco products, or premarket notification for devices has been made publicly available, the release of the environmental document before approval or authorization of human drugs, animal drugs, biologic products, devices and tobacco products is inconsistent with statutory requirements imposed on FDA. Appropriate environmental documents, comments, and responses will be included in the administrative record to the extent allowed by applicable laws.

8. Amend § 25.52 by revising the first sentence of paragraph (a) and paragraphs (b) and (c) to read as follows:

§ 25.52 Environmental impact statements.

(a) If FDA determines that an EIS is necessary for an action involving investigations, approvals, or market authorizations for drugs, animal drugs, biologic products, devices, or tobacco products, an EIS will be prepared but will become available only at the time of the approval or market authorization of the product. * * *

(b) Comments on the EIS may be submitted after the approval or market authorization of the drug, animal drug, biologic product, device, or tobacco product. Those comments can form the basis for the Agency to consider beginning an action to withdraw the approval or market authorization of applications for a drug, animal drug, biologic product, or tobacco product, or to withdraw premarket notifications or premarket approval applications for devices.

(c) In those cases where the existence of applications and premarket notifications for drugs, animal drugs, biologic products, devices, or tobacco products has already been disclosed before the Agency approves the action, the Agency will ensure appropriate public involvement

consistent with 40 CFR 1506.6 and part 1503 in preparing and implementing the NEPA procedures related to preparing EISs while following its own disclosure requirements including those listed in part 20 and §§ 312.130(b), 314.430(d), 514.11(d), 514.12(b), 601.51(d), 807.95(e), 812.38(b), and 814.9(d) of this chapter.

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Dated: September 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-24219 Filed: 9/23/2015 08:45 am; Publication Date: 9/24/2015]